Diazinon Registrant Comments

- Label changes and use information
- Monitoring data
- Risk characterization
- Modeling Inputs
- Aquatic toxicity endpoints
- Olfactory impairment



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Diazinon Use Information

Since 2000, Diazinon use nationwide has dropped by more than 90%.

Background

- Pre 2000: Diazinon use nationwide totaled roughly 13 million pounds annually.
- 70% of all use was for household lawn and garden pest control.
- 5% of all use was for crack & crevice and for flea collars.
- 25% of all use was for agricultural applications.

Background: Elimination of Residential Uses

- December 2000: EPA and the registrants signed a Memorandum of Agreement (MOA) to phase out and cancel all residential uses according to the following schedule.
 - All indoor residential uses were cancelled in March of 2001. Retail sales of existing stocks of these products ended on December 31, 2002.
 - All outdoor residential uses were cancelled with distribution to retailers ending in September of 2003. Retail sales of existing stocks of these products ended on December 31, 2004.
- After 12/31/04, a buy-back program prevented further sales of existing stocks.

Background: Limitation of Food Crop Uses

- The MOA also began the process to cancel 20 different uses on food crops.
- In July of 2002, EPA issued an Interim Reregistration Eligibility Decision which proposed significant changes to the remaining labeled crops, including use deletions and additional restrictions.
- EPA completed the Diazinon RED in July of 2006.

Resulting Changes in Diazinon Use

- In 2000, EPA estimated that 25% of the 13 million pounds of diazinon applied annually 3.25 million pounds –was for agricultural applications.
- The IRED changes have brought total use today to less than 750,000 pounds annually.

IRED Food Crop Label Mitigation

- Cancellation of all granular registrations. The only exception are two current Section 24(c) registrations held by Washington and Oregon for control of the cranberry girdler. Granular use on lettuce will only be allowed in California until 2008.
- Deletion of aerial application for all uses. (Except for lettuce in California)
- Deletion of foliar application on all vegetable crops.
 The only exception will be for treatment of leafhopper on honeydew melons and in California and gensing.

IRED Label Mitigation

- Reduction in the number of applications of diazinon per growing season. On most uses only one application per growing season will be allowed. Crops with dormant season and in season uses (e.g., stone fruits) will have one application per season for a total of two applications per year.
- Application rate reduction. The maximum rate for ornamentals (except cut flowers) will be reduced from 2 lb ai/acre to 1 lb ai/acre. The maximum granular rate for lettuce will be reduced from 4 lb ai/acre to 1 lb ai/acre.
- Cancellation of all seed treatment uses. Five uses will be cancelled: beans (snap), beans (lima), corn (field), corn (sweet), and green peas.

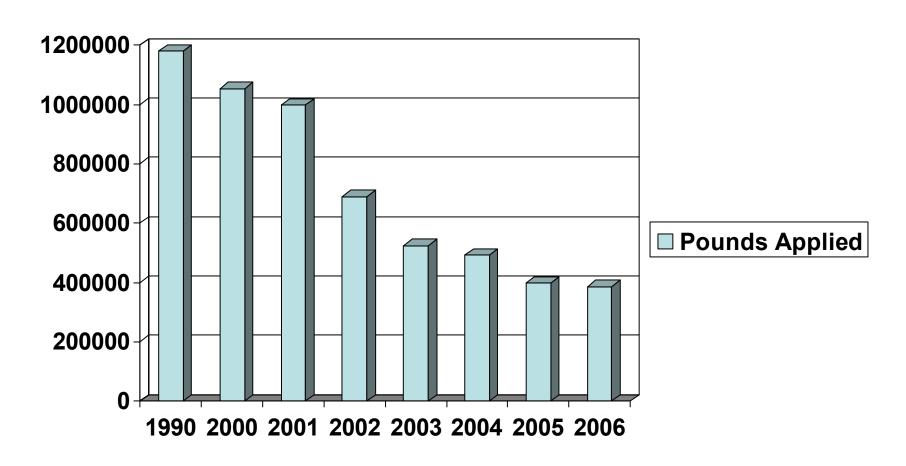
IRED Label Mitigation

- Application limitations and labeling on orchard crops. For all orchard crops (nuts, stone fruits, pome fruits, etc) with dormant season uses, for most crops label language only allows applications every other year unless pest pressures are such that consecutive, annual treatments are necessary.
- Cancelled uses. Section 3 uses: Chinese broccoli, Chinese cabbage, Chinese mustard, Chinese radish, corn, grapes, hops, mushrooms, sugar beets and walnuts.

Substantial Data Documents Diazinon Use in California

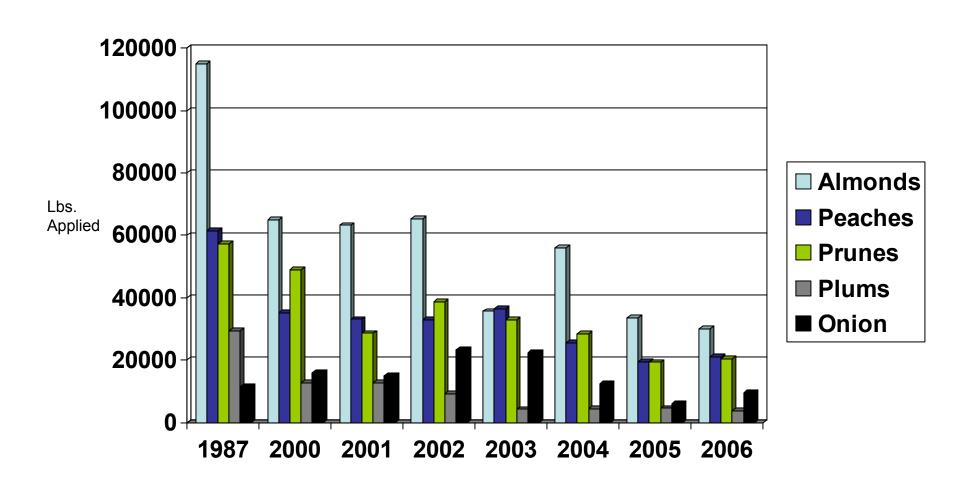
- Represents 70% of total use.
- California has had mandatory pesticide recordkeeping and reporting since 1990.
- Data is available at http://calpip.cdpr.ca.gov/cfdocs/calpip/prod/main.cfm

Diazinon Use in California



Source: California Pesticide Use Reports

Changes on Key CA Crops



Source: CA Pesticide Use Reports

Coalition for Urban/Rural Environmental Stewardship (CURES)

- Industry-supported stewardship program
- Developed Diazinon-specific best management practices for dormant season applications in California.
- BMPs included:
 - Development and maintenance of a 10-foot buffer strip for orchards that are adjacent to and within 100 feet of a sensitive aquatic site.
 - Restrictions on applications made 100 feet upslope of a sensitive aquatic site.
 - Use of ground application equipment only
 - Sprays must be directed away from sensitive aquatic sites.
 - No applications when soil moisture is at field capacity
- These practices now required by state water quality regulators (CVRWQCB) and CDPR dormant spray regulations

County Bulletin Restrictions in CA

The following restrictions in place in all but two counties in California:

- 1. Do not use in currently occupied habitat (some exceptions for specific species).
- 2. Provide a 20 foot minimum strip of vegetation (on which pesticides should not be applied) along rivers, creeks, streams, wetlands, vernal pools and stock ponds or on the downhill side of fields where run-off could occur. Prepare land around fields to contain run-off by proper leveling, etc. Contain as much water "onsite" as possible. The planting of legumes, or other cover crops for several rows adjacent to off-target water sites is recommended. Mix pesticides in areas not prone to runoff such as concrete mixing/loading pads, disked soil in flat terrain or graveled mix pads, or use a suitable method to contain spills and/or rinsate. Properly empty and triple-rinse pesticide containers at time of use.

County Bulletin Restrictions in CA

- 3. Conduct irrigations efficiently to prevent excessive loss of irrigation waters through run-off. Schedule irrigations and pesticide applications to maximize the interval of time between the pesticide application and the first subsequent irrigation. Allow at least 24 hours between application of pesticides listed in this bulletin and any irrigation that results in surface run-off into natural waters. Time applications to allow sprays to dry prior to rain or sprinkler irrigations. Do not make aerial applications while irrigation water is on the field unless surface run-off is contained for 72 hours following the application.
- 4. For sprayable or dust formulations: when the air is calm or moving away from habitat, commence applications on the side nearest the habitat and proceed away from the habitat. When air currents are moving toward habitat, do not make applications within 200 yards by air or 40 yards by ground upwind from occupied habitat. The county agricultural commissioner may reduce or waive buffer zones following a site inspection, if there is an adequate hedgerow, windbreak, riparian corridor or other physical barrier that substantially reduces the probability of drift.

Summary

- Since 2000, Diazinon use has plummeted from 13 million pounds annually to less than 750,000 pounds today.
- IRED/RED label mitigation has already addressed ESA issues through the cancellation of crops, changes in label rates and number of applications, deletion of aerial uses and other measures.
- Buffers are already in place.

The Monitoring Data in the Draft BiOp Does Not Represent Current and Future Conditions

Overview

- NMFS discussion of monitoring data relies on outdated data (1990s, early 2000s); not reflective of current uses
- No discussion of substantial reductions in diazinon detects as RED changes were implemented
- No quantitative use of of monitoring data
 - No frequency distributions (e.g., 80th, 90th, 95th percentiles)
 - No discussion of percentage of detects above benchmark concentrations (e.g., 0.01 ug/L, 0.1 ug/L, 1.0 ug/L)
 - No clear indication of whether max values relied on are from representative salmon waters (Some max values appear to be either concentrations in runoff rather than streams or drainage ditches - not salmon habitat)
 - No temporal component of occurences
- Instead, a qualitative discussion of ranges and max values

Updated Water Monitoring Data

- Updated through 2006
- Number and percent diazinon detects
 - **2001: 133; 43.61%**
 - **2002: 684; 40.76%**
 - **2003: 607; 34.63%**
 - **2004: 294; 23.05%**
 - **2005: 86; 13.83%**
 - **2006: 42; 7.64%**

*NAWQA Cycle 2 Data

Updated Water Monitoring Data NAWQA Cycle II Data

(http://water.usgs.gov/nawqa)

- Distribution of diazinon detects 2001-2004 (as percent of samples for land use category)
 - Agricultural
 - All: **14.14%**; >0.01 ug/L: 4.94%; >0.10 ug/L: 0.38%; >1.0 ug/L: 0.00%;
 - Range 0.0007 0.53
 - Urban
 - All: **71.85%**; >0.01 ug/L: 49.11%; >0.10 ug/L: 6.67%; >1.0 ug/L: 0.00%
 - Range 0.0013 0.78
 - Other
 - All: **26.76%**; >0.01 ug/L: 13.96%; >0.10 ug/L: 0.1.99%; >1.0 ug/L: 0.00%
 - Range 0.0017 0.36
 - Mixed
 - All: **34.38%**; >0.01 ug/L: 14.37%; >0.10 ug/L: 0.32%; >1.0 ug/L: 0.00%
 - Range 0.0010 0.33

Updated Water Monitoring Data NAWQA Cycle II Data

(http://water.usgs.gov/nawqa)

- Distribution of detects 2004-2006 (as percent of samples for land use category)
 - Agricultural
 - All: **2.5%**; >0.01 ug/L: 2.0%; >0.10 ug/L: 0.60%; >1.0 ug/L: 0.00%;
 - Range 0.0048 0.50
 - Urban
 - All: **25.4%**; >0.01 ug/L: 2.6%; >0.10 ug/L: 0.00%; >1.0 ug/L: 0.00%
 - Range 0.0038 0.11
 - Other
 - All: **10.5%**; >0.01 ug/L: 1.8%; >0.10 ug/L: 0.15%; >1.0 ug/L: 0.00%
 - Range 0.004 0.50
 - Mixed
 - All: **7.6%**; >0.01 ug/L: 1.5%; >0.10 ug/L: 0.30%; >1.0 ug/L: 0.00%
 - Range 0.0036 0.029

*NAWQA Cycle 2 Data

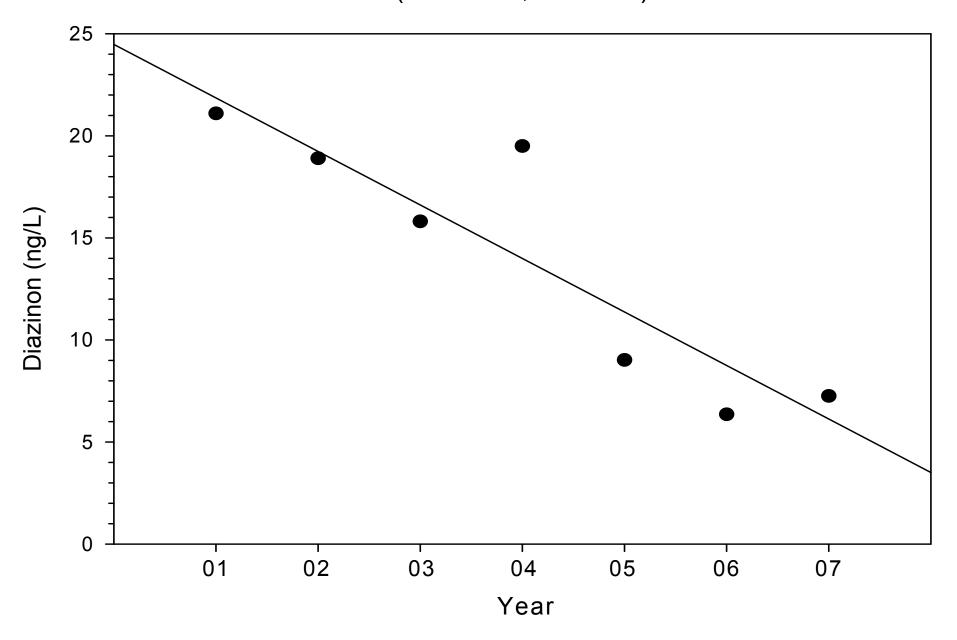
Better Monitoring Data is Readily Available (Per Draft BiOp, page 226, line 1 and 2)

- The report correctly states that diazinon monitoring data may not be representative of current and future uses and conditions
- Older diazinon monitoring data report higher concentrations than more current data and should not be used to assess ecological risk to salmonids (see Hall 2003a, Hall 2003b, Hall and Anderson, 2008)

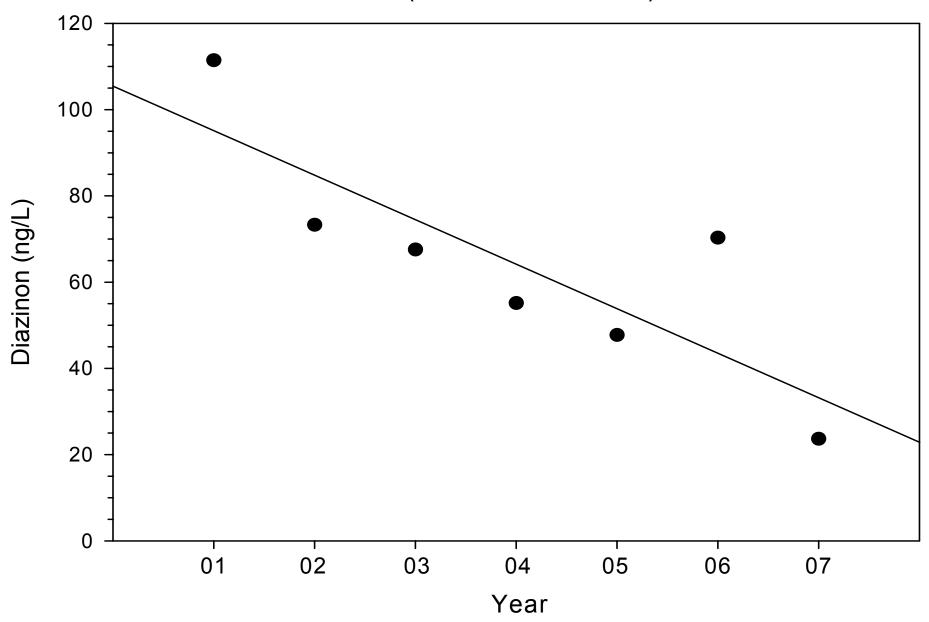
More on Currently-Available Monitoring Data (Draft BiOp, page 225, Table 40)

- Trends analysis of current San Joaquin watershed data (01-07) is in progress; initial review of data shows a large % of non-detects
- Hall et al. 2003b have reported declining concentrations of diazinon in the Sacramento River watershed from 1991 to 2001
- Updated trends analysis for the Sacramento River watershed (2001 to 2007) has also shown further significant declines in both diazinon concentrations and target exceedances (Hall and Anderson, 2008)

Diazinon Mean Concentrations by Year for all Sacramento and Feather River Mainstem Sites $(r^2 = .813; P=.006)$



Diazinon Mean Concentrations by Year for all Sacramento and Feather River Tributary Sites $(r^2 = .665; P=.025)$



Washington State SW Monitoring (2003 – 2005) Burke et al., 2006

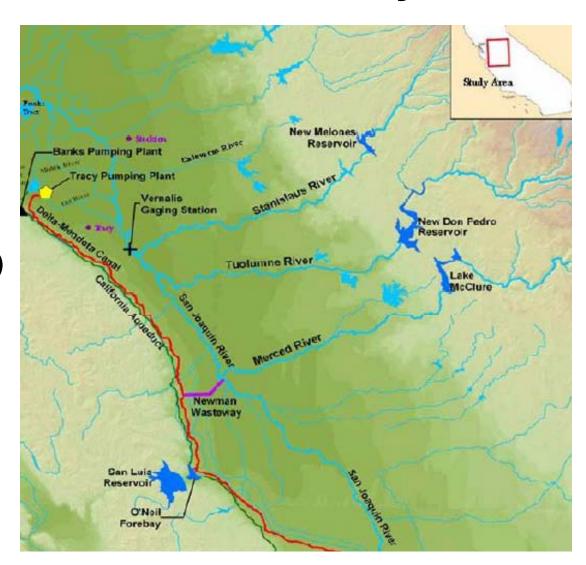
- Monitoring in salmonid-bearing streams during pesticide use season
- 1 urban and 3 agricultural watersheds within critical habitats
- Only 1 diazinon detection (0.21 ppb*) out of 78 samplings in urban watershed exceeded chronic invertebrate water quality criterion; RQs for rainbow trout never exceeded
- In urban watershed, detection frequency declined from 39% (2003) to 3% (2005) due to cancelling homeowner uses in 2004
- In agricultural watersheds, max concentration 0.023 ppb out of 125 samplings; no water quality exceedances
- *Apparent 0.21 ppb detection attributable to diuron, not diazinon in reporting table.
 Diazinon max concentration 0.095 ppb.

Monitoring Values not relevant to Salmonid Risk Assessment: Newman Wasteway

Maximum diazinon value of 36.8 ug/L for Rivers is incorrect.

This value was reported for Newman Wasteway (drain/tributary) of the San Joaquin River Watershed

Newman wasteway is not a habitat for salmonids





Newman Wasteway

1.5 Miles are concrete lined

7.5 miles are natural

Subject of 2004 Bureau of Reclamation
Recirculation Pilot Study to purge accumulating sediment



Orestimba Creek

Maximum value of 29.371 ug/L was reported from Orestimba Creek during 1996/1997

 Older diazinon monitoring data are not valid based on current use patterns



Salinas Valley

The use of maximum diazinon concentrations of 67 ug/L for the Salinas Valley is inappropriate.

- The Salinas Valley value was reported from an ag ditch that is:
 - not a habitat for salmonids,
 - Based on a value from early '90s that does not represent current use patterns,
 - the analytical method for analysis
 (ELISA) is questionable.



Rationale for Employing Modeling Is Flawed (Draft Bi-Op, page 225, Point #1)

- The statement that diazinon monitoring data were not designed to capture peak values is partly incorrect
 - CA monitoring data from 1991 to 2007 included measurements from some stream sites located beside ag fields where diazinon was applied during the wet season
 - Therefore, for at least some sites maximum values were reported

Rationale for Employing Modeling Is Flawed (Draft Bi-Op, page 226, Para. 3, lines 5-7)

- The statement that sampling for these studies was not conducted in coordination with specific applications of diazinon is incorrect.
- As stated above, diazinon concentrations at some stream sites were measured after application and the first major storm event

Concern With Sediment Concentration Requires Reconsideration (Draft Bi-Op, page 228, Table 44

- Sediment diazinon concentrations (3,916,689 ng/kg dw) are suspect and need to be carefully checked.
- Well documented physical and chemical properties of diazinon reported in various documents (including page 203 of draft BiOP) state that this insecticide is not expected to strongly adsorb to sediment.

References

- Hall, L.W. Jr. 2003a. Historical analysis of diazinon from the San Joaquin River watershed with implications for exceeding water quality targets. CA Fish and Game 89:1-19.
- Hall, L. W. Jr. 2003b. Analysis of diazinon monitoring data from the Sacramento and Feather River watersheds:1991-2001. Environ. Mont. Assess. 86: 233-253.
- Hall, L. W. Jr and R. D. Anderson. 2008. Analysis of diazinon environmental monitoring data from the Sacramento and Feather River watershed: 2001-2007. Final report, University of Maryland, Wye Research and Education Center, Queenstown, MD.

Concerns Regarding Risk Characterization

Overview of Risk Characterization

- NMFS approach relies on screening model estimates of environmental concentrations
- Monitoring data from USGS NAWQA and State of California are reported, but emphasis placed on maximum concentrations rather than mean and median concentrations. In fact, highest detects found in regions not relevant to salmonid habitats
- Further assessment involves endpoints such as invertebrate food sources, prey survival, growth, reproduction, swimming and olfactory-mediated behaviors.
 - Impact on populations has not been established.

Exposure Issues

Exposures based on modeling and monitoring.

- Modeling Issues
 - For diazinon, 7 crops modeled but only one (almonds) used western-states scenario. Unrealistic for Pacific salmonids and steelhead because, except for almonds, crop scenarios have more runoff than will occur in Pacific states. In addition, aerial applications have been eliminated for all crops and application rates, and repeat applications have been reduced. These steps will lead to substantially reduced deposition of diazinon in adjacent water bodies.
 - Exposure models based on a farm pond. Very unrealistic for streams and rivers relevant to habitat of salmonids. (Turner 2002)

PRZM-EXAMS and GENEEC Modeling

Conceptual model:

- 10 ha treated field surrounds and directly abuts a 1ha surface area, 2-m deep stagnant pond (USDA farm pond)
- EPA-EFED Default: No buffer between pond, field; models cannot account for run off reductions due to buffers
- Pond assumed to be directly downwind of treated field (maximize drift)
- No inflow or outflow of water
- Pesticide assumed to be instantaneously and homogeneously distributed throughout pond
- Maximize runoff slopes (runoff loading)

Conceptual model does not simulate off-site transport to salmon habitat

The Appropriate Application of PRZM-EXAMS and GENEEC Screening Models

- What the output tells you: If EECs are below effect concentrations, high confidence of a low potential for adverse effects;
- But: If EECs exceed effect concentrations, this does not mean a high potential for adverse effects under actual use conditions – it means that the assessment needs to be refined

Flaws in NMFS Modeling Inputs

- All modeling based on obsolete labels (pre-EPA RED)
- Does not account for significant reductions in use, use phase-outs negotiated during RED process
- Only 1 of 7 modeling scenarios applicable to Pacific salmon (CA almonds); remainder of scenarios are east coast or midwest scenarios that are irrelevant to Pacific salmon
 - East coast, midwest scenarios feature heavier rainfall than west coast scenarios
 - Aquatic loading for east coast, midwest scenarios driven by run off loading
 - Drift loading significant for west coast scenarios

Weakness of Effects Data for Fish --Generally

- Survival data: No species sensitivity distributions, even for salmonid species despite multiple tests
- Selected endpoints include several sublethal endpoints based on literature data
 - Literature data of questionable quality
 - Have not been able to reproduce some effects reported in the literature (e.g., olfactory results)
- LC50 testing conducted with fish ranging from approximately 0.5 g to 5.0 g (EPA FIFRA guideline)
 - Sensitive life stage
 - Tested life stage not related to size, life stages of salmon

Weakness of Effects Data for Fish – Diazinon Specific

Growth data:

- Rely only on 1977 Allison and Hermanutz trout partial life cycle (274 day continuous exposure) study
 - Most sensitive endpoint: Hatching of F1 fish from exposed F0 parents; Growth of F1 from exposed F0 parents
- Ignored more relevant, recent chronic studies
 - Minnow full lifecycle (NOEC: 3 ug/L)
 - Minnow ELS
 - NOEC: 90 ug/L
 - Most sensitive endpoint: larval growth
 - NOEC for egg hatching and larval survival: 1.6 mg/L (Highest Conc. Tested.)
 - Minnow partial lifecycle (reported NOEC 3.5 ug/L; EFED NOEC 0.92 ug/L)

Weakness of Effects Data for Fish – Diazinon Specific

- Mesocosm data ignored
 - Highly sensitive species tested (bluegill sunfish)
 - No effects on spawning, survival, growth at concentrations up to 34 ug/L (HCT)
 - More representative of potential effects under field conditions than laboratory continuous exposure tests
- No discussions of recovery from transient sublethal effects (e.g., swimming, olfaction)
- Considerable speculative discussions concerning effects of pesticide mixtures (chlorpyrifos, diazinon, malathion) on fish

Diazinon and Sublethal Effects on Salmonids

Swimming

– Concentration of diazinon needed to produce effects on swimming barely overlapped with exposure concentrations based on modeling and monitoring. Thus, the effect of diazinon on swimming behavior of salmonids should be considered minimal, if at all relevant. Effects seen only at 500 ppb.

Olfaction

 Moore and Waring, 1996 has been dismissed by EPA because test system could not be quantitatively related to exposures in the natural environment.

Diazinon and Adverse Effects on Salmonids

- Olfaction continued
 - Scholz et al., 2000 showed potential effects of diazinon on Chinook salmon behavior on a nominal diazinon concentration of 1 ppb.
 - The authors indicated that the results were preliminary with regard to homing behavior
 - Results not reproducible:
 - Palm & Powell, Presentation to Society of Environmental Toxicology & Chemistry. November 2007"
 - Since the presumption that diazinon causes salmonids to have impaired olfaction at very low concentrations is based essentially on a single study, the "effect" is not sufficiently demonstrated to support reliable risk assessment.

Diazinon and Indirect Adverse Effects on Salmonids

- Aquatic Invertebrate Food Sources
 - Diazinon is highly toxic to aquatic invertebrates.
 - Wide range of sensitivities among various invertebrate species
 - LC₅₀s is five orders of magnitude (Table 50).
 - This suggests that while some aquatic invertebrates could be severely impacted by exposure to diazinon, others would be relatively unaffected and would serve as alternative food sources.

Diazinon and Indirect Adverse Effects on Salmonids

- Aquatic Invertebrate Food Sources (cont.)
- Invertebrate populations undergo natural changes in numbers, composition throughout a season
- Fish are opportunistic feeders, will change prey and forage on a wide variety of invertebrate species
- The draft BiOp assumes a domino effect, but offers no data to support hypothesis
- No matching of monitoring data for salmon streams to invertebrate effect concentrations
 - Corroborated by Giddings et al., 2000 " Ecological Risks of Diazinon from Agricultural Use in the Sacramento-San Joaquin River Basins, California" Risk Analysis, 20(5),2000,pp. 545-572.

Summary

 It would have been more meaningful to compare distributions of recently monitored diazinon water concentrations found in bona-fide salmonid habitats with differing sensitivities of salmonid species as well as sensitivities of their potential prey to diazinon in order to generate a probabilistic interpretation of risk to salmonid populations.

Summary

 Because of the significant limitations with exposure modeling, and the wealth of monitoring data from salmonid-relevant habitat, it is obvious that monitoring data for diazinon should be the main component of the risk characterization.

Appropriate Monitoring Values for Risk Assessment

- Eliminate high concentration that are not from salmon habitat
 - 36.8 ppb: Newman Wasteway
 - 67 ppb: Salinas Valley agricultural drain
 - 29.4 ppb: Orestimba Creek- ephemeral stream created from ag field irrigation return water
- Use current monitoring data
 - Highest relevant detect from NAWQA II
 - Water Monitoring is 0.5 ppb,
 - Use mean concentrations; 0.084 ppb (NAWQA) and 0.159 ppb (Cal.)
 - Apply appropriate end-points i.e. Survival Rainbow Trout
 LC₅₀ = 90 ppb
 - Apply EPA Endangered Species LOC = 4.5 ppb
- Relevant detections are well below Level of Concern

Assessment of Olfactory Effects in Salmon

ALARM SUBSTANCE RECOGNITION AND PREDATOR AVOIDANCE BY CHINOOK SALMON (ONCORHYNCHUS TSCHAWYTSCHA) FOLLOWING EXPOSURE TO AN ORGANOPHOSPHATE PESTICIDE

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- •Two controlled laboratory studies were presented at the annual meeting of the Society of Environmental Toxicology & Chemistry in November of 2007 (currently in review for publication in Environmental Toxicology and Chemistry)
- •Attempt to reproduce results of Scholz et al. 2002 relating to olfactory mediated behaviors of Chinook Salmon exposed to Diazinon

Research Rationale

- •Study reports show diazinon to affect physiology and behavior associated with olfaction.
- •A loss of olfaction can be detected by changes in avoidance behaviors.
- •A reduced ability to detect alarm scents could increase their susceptibility to predation.

Study 1: Effects of Diazinon on the Olfactory Function and Behavior of Chinook Salmon in Two-Choice Maze Systems

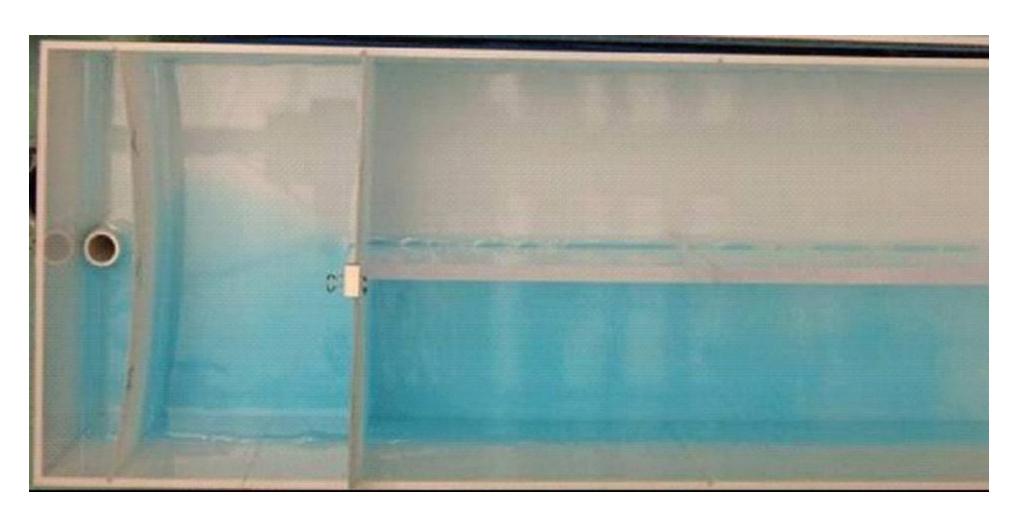
Study 2: Predator Avoidance by Juvenile Chinook Salmon Following Exposure to Diazinon and Alarm Scents

David B. Powell, Ph.D. Roger C. Palm, Ph.D.

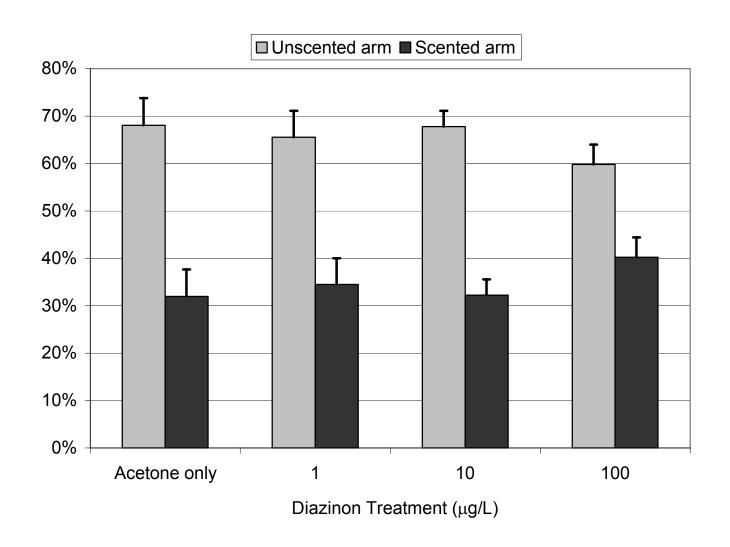
Study 1: Design

- Chinook salmon juveniles
- •2 hour Diazinon exposure (0, 1, 10 or 100 μg/L)
- •10 salmon per Y-maze test
- •20 runs per treatment dose
- Chinook skin extract (alarm substance)

Study 1: Food grade dye demonstrates path of "alarm" scents



Proportion of Diazinon-treated Chinook Salmon Choosing Water Containing Skin Extract Alarm Scent



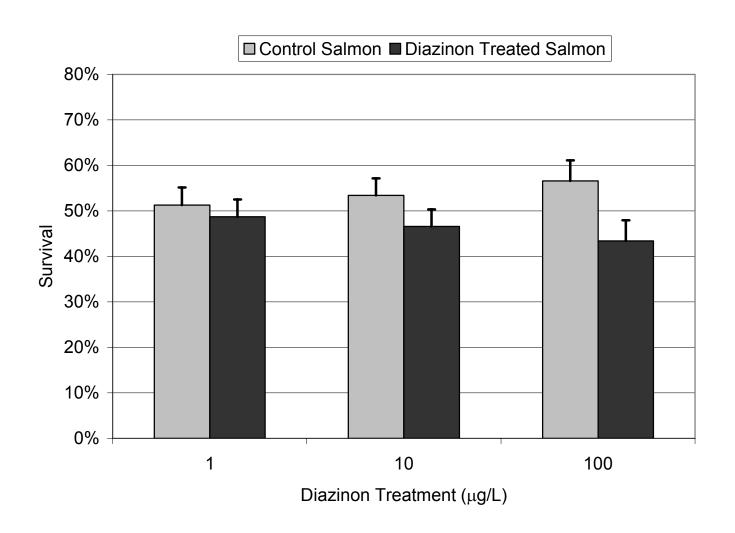
Study 1: Conclusions

- None of the diazinon-exposed treatment groups differed from the respective control groups (ANOVA, p>0.05).
- These results suggest that environmentally relevant levels of diazinon do not significantly impair olfaction in chinook salmon.

Study 2: Design

- Chinook salmon prey and rainbow trout predators
- Olfactory cues: chinook skin extract and predator fish scent
- Randomized design, 50% untreated prey
- Predation target = 50% consumption
- 12 tests per Diazinon dose, 20 salmon/test

Control and Diazinon-treated Chinook Salmon Surviving Predation Following a Skin Extract Alarm Scent Warning



Study 2: Conclusions

- No significant difference in survival was detected between any treatment group and its control (ANOVA, p>0.05)
- None of the 3 diazinon-exposed groups differed from either of the other 2 (p>0.05)
- Results also suggest diazinon exposure at these levels does not impair any physiological or behavioral mechanism that may be important for predator avoidance